Package leaflet: Information for the patient

Cresemba 200 mg powder for concentrate for solution for infusion
isavuconazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cresemba is and what it is used for

What Cresemba is
Cresemba is an anti-fungal medicine that contains the active substance isavuconazole.

How Cresemba works
Isavuconazole works by killing or stopping the growth of the fungus, which causes the infection.

What Cresemba is used for
Cresemba is used in patients from 1 year of age and older to treat the following fungal infections:
- invasive aspergillosis, caused by a fungus in the 'Aspergillus' group;
- mucormycosis, caused by a fungus belonging to the 'Mucorales' group in patients for whom a treatment with amphotericin B is not appropriate.

2. What you need to know before you use Cresemba

Do not use Cresemba:
- if you are allergic to isavuconazole or any of the other ingredients of this medicine (listed in section 6),
- if you have a heart beat problem called 'familial short QT syndrome',
- **if you are using any of the following medicines:**
  - ketoconazole, used for fungal infections,
  - high doses of ritonavir (more than 200 mg every 12 hours), used for HIV,
  - rifampicin, rifabutin, used for tuberculosis,
  - carbamazepine, used for epilepsy,
  - barbiturate medicines like phenobarbital, used for epilepsy and sleep disorders,
  - phenytoin, used for epilepsy,
  - St John's wort, a herbal medicine used for depression,
  - efavirenz, etravirine, used for HIV,
  - nafcillin, used for bacterial infections.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Cresemba:

- if you have had an allergic reaction to other 'azole' anti-fungal treatments in the past, such as ketoconazole, fluconazole, itraconazole, voriconazole or posaconazole,
- if you are suffering from severe liver disease. Your doctor should monitor you for possible side effects.

Look out for side effects

Stop using Cresemba and tell your doctor straight away if you notice any of the following side effects:

- sudden wheezing, difficulty breathing, swelling of the face, lips, mouth or tongue, severe itching, sweating, dizziness or fainting, fast heartbeat or pounding in the chest – these may be signs of a severe allergic reaction (anaphylaxis).

Problems while having Cresemba as drip into a vein

Tell your doctor straight away if you notice any of the following side effects:

- low blood pressure, feel short of breath, nausea, dizziness, headache, tingling – your doctor may decide to stop the infusion.

Changes in your liver function

Cresemba can sometimes affect your liver function. Your doctor may carry out blood tests while you are taking this medicine.

Skin problems

Tell your doctor straight away if you get severe blistering of the skin, mouth, eyes or genitals.

Children and adolescents

Do not give Cresemba to children younger than 1 year, because there is no information on use in this age group.

Other medicines and Cresemba

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Some medicines may affect the way Cresemba works or Cresemba may affect the way they work, if they are taken at the same time.

In particular, do not take this medicine and tell your doctor or pharmacist if you are taking any of the following medicines:

- ketoconazole, used for fungal infections,
- high doses of ritonavir (more than 200 mg every 12 hours), used for HIV,
- rifampicin, rifabutin, used for tuberculosis,
- carbamazepine, used for epilepsy,
- barbiturate medicines like phenobarbital, used for epilepsy and sleep disorders,
- phenytoin, used for epilepsy,
- St John's wort, a herbal medicine used for depression,
- efavirenz, etravirine, used for HIV,
- nafcillin, used for bacterial infections.

Unless your doctor tells you otherwise, do not take this medicine and tell your doctor or pharmacist if you are taking any of the following medicines:

- rufinamide or other medicines which decrease the QT interval on the heart tracing (ECG),
- aprepitant, used to prevent nausea and vomiting by cancer treatment,
- prednisone, used for rheumatoid arthritis,
- pioglitazone, used for diabetes.

Tell your doctor or pharmacist if you are taking any of the following medicines, as a dose adjustment or monitoring may be required to check that the medicines are still having the desired effect:

- ciclosporin, tacrolimus and sirolimus, used to prevent rejection of a transplant,
- cyclophosphamide, used for cancer,
- digoxin, used to treat heart failure or an uneven heart beat,

- colchicine, used for gout attack,
- dabigatran etexilate, used to stop blood clots after hip or knee replacement surgery,
- clarithromycin, used for bacterial infections,
- saquinavir, fosamprenavir, indinavir, nevirapine, lopinavir/ritonavir combination, used for HIV,
- alfentanil, fentanyl, used against strong pain,
- vincristine, vinblastine, used for cancer,
- mycophenolate mofetil (MMF), used in transplant patients,
- midazolam, used for severe insomnia and stress,
- bupropion, used for depression,
- metformin, used for diabetes,
- daunorubicin, doxorubicin, imatinib, irinotecan, lapatinib, mitoxantrone, topotecan, used for different sorts of cancer.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Do not take Cresemba if you are pregnant, unless your doctor tells you otherwise. This is because it is not known if it may affect or harm your unborn baby.

Do not breast-feed if you are taking Cresemba.

Driving and using machines
Cresemba may make you feel confused, tired or sleepy. It can also make you pass out. Therefore, be very careful when driving or operating machinery.

3. How to use Cresemba

Cresemba will be given to you by a doctor or nurse.

The recommended dose is as follows:

	Starting dose for the first two days (every 8 hours for the first 48 hours) [1]	**Maintenance dose after the first two days (once a day) [2]**
Adults	200 mg isavuconazole (one vial)	200 mg isavuconazole (one vial)
Adolescents and children with an age from 1 year to less than 18 years		
Bodyweight < 37 kg	5.4 mg/kg isavuconazole	5.4 mg/kg isavuconazole
Bodyweight ≥ 37 kg	200 mg isavuconazole (one vial)	200 mg isavuconazole (one vial)
[1] Six administrations in total. [2] This is started 12 to 24 hours after your last starting dose.		

You will be given this dose until your doctor tells you otherwise. The duration of treatment with Cresemba may be longer than 6 months if your doctor considers this necessary.

The vial will be given as a drip into a vein by your doctor or nurse.

If you use more Cresemba than you should
If you think you have been given too much Cresemba, talk to your doctor or nurse straight away. You may have more side effects such as:
- headache, feeling dizzy, restless or sleepy,
- tingling, reduced sense of touch or sensation in the mouth,
- problems being aware of things, hot flushes, anxiety, joint pain,
- changes in the way things taste, dry mouth, diarrhoea, vomiting,
- feeling your heart beat, faster heart rate, being more sensitive to light.

If you forget to use Cresemba
As you will be given this medicine under close medical supervision, it is unlikely that a dose would be missed. However, tell your doctor or nurse if you think that a dose has been forgotten.

If you stop using Cresemba
Cresemba treatment will continue for as long as your doctor tells you. This is to make sure that the fungal infection has gone.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Cresemba and tell your doctor straight away if you notice any of the following side effects:
- a severe allergic reaction (anaphylaxis) such as sudden wheezing, breathing problems, swelling of the face, lips, mouth or tongue, severe itching, sweating, dizziness or fainting, fast heartbeat or pounding in the chest.

Tell your doctor straight away if you notice any of the following side effects:
- severe blistering of the skin, mouth, eyes or genitals.

Other side effects
Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Common: may affect up to 1 in 10 people
- low potassium in your blood,
- decreased appetite,
- confusion (delirium),
- headache,
- sleepiness,
- inflamed veins that could lead to blood clots,
- shortness of breath or sudden and severe difficulty breathing,
- feeling sick (nausea), being sick (vomiting), diarrhoea, stomach pain,
- changes in blood tests of liver function,
- rash, itching,
- kidney failure (symptoms could include swelling of legs),
- chest pain, feeling tired or sleepy,
- problems where the injection was given.

Uncommon: may affect up to 1 in 100 people
- reduced white blood cells - can increase your risk of infection and fever,
- reduced blood cells called ‘platelets’ - can increase your risk for bleeding or bruising,
- reduced red blood cells - can make you feel weak or short of breath or make your skin pale,
- severe reduction in blood cells - can make you feel weak, cause bruising or make infections more likely,
- rash, swelling of your lips, mouth, tongue or throat with difficulty breathing (hypersensitivity),
- low blood sugar levels,
- low blood levels of magnesium,
- low levels in the blood of a protein called ‘albumin’,
- not getting the right goodness from your diet (malnutrition),
- low blood levels of sodium (hyponatraemia),
- depression, difficulty sleeping,

- seizure, fainting or feeling faint, dizziness,
- sensation of tingling, tickling, or pricking of the skin (paraesthesia),
- altered mental state (encephalopathy),
- changes in taste (dysgeusia),
- feeling of 'spinning' or being dizzy (vertigo),
- heart beat problems - may be too fast or uneven, or extra heart beats – this may show in your heart tracing (electrocardiogram or ECG),
- problems with the blood circulation,
- low blood pressure,
- wheezing, very fast breathing, coughing up blood or blood-stained sputum, nose bleeding,
- indigestion,
- constipation,
- feeling bloated (abdominal distension),
- enlarged liver,
- inflammation of the liver,
- problems with the skin, red or purple spots on the skin (petechiae), inflamed skin (dermatitis), hair loss,
- back pain,
- swelling of the extremities,
- feeling weak, very tired, or sleepy or generally out of sorts (malaise).

Side effects with frequency not known:
- anaphylaxis (a severe allergic reaction).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cresemba

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cresemba contains
- The active substance is isavuconazole. Each vial contains 372.6 mg isavuconazonium sulfate, corresponding to 200 mg isavuconazole.
- The other ingredients (excipients) are mannitol (E421) and sulfuric acid.

What Cresemba looks like and contents of the pack
Cresemba 200 mg is presented in a single use glass vial as a powder for concentrate for solution for infusion.

Marketing Authorisation Holder:

Basilea Medical Ltd.
Onslow House
Onslow Street
Guildford
GU1 4TL
United Kingdom

Manufacturer:

Almac Pharma Services (Ireland) Limited
Finnabair Industrial Estate
Dundalk, Co. Louth
A91 P9KD
Ireland

Almac Pharma Services Limited
Seagoe Industrial Estate
Craigavon, Co. Armagh
BT63 5UA
United Kingdom

For any information about this medicine, please contact:
Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Telephone 01304 616161.

This leaflet was last revised in 07/2025.

The following information is intended for healthcare professionals only:

Cresemba 200 mg powder for concentrate for solution for infusion must be reconstituted and diluted prior to infusion.

Reconstitution

One vial of the powder for concentrate for solution for infusion should be reconstituted by addition of 5 mL water for injection to the vial. The reconstituted concentrate contains 40 mg isavuconazole per mL. The vial should be shaken to dissolve the powder completely. The reconstituted solution should be inspected visually for particulate matter and discoloration. Reconstituted concentrate should be clear and free of visible particulate. It must be further diluted prior to administration.

Dilution

Adults and paediatric patients with bodyweight from 37 kg:

After reconstitution, the entire content of the reconstituted concentrate should be removed from the vial and added to an infusion bag containing 250 mL of either sodium chloride 9 mg/mL (0.9%) solution for injection or 50 mg/mL (5%) dextrose solution. The infusion solution contains approximately 0.8 mg isavuconazole per mL.

Paediatric patients with bodyweight below 37 kg:

The final concentration of the infusion solution should be in the range of 0.4 to 0.8 mg isavuconazole per mL. Higher concentrations should be avoided as these may cause local irritation at the site of infusion.
To obtain the final concentration, the appropriate volume of the reconstituted concentrate based on paediatric dosing recommendations (see section 3) should be removed from the vial and added to an infusion bag containing the appropriate amount of diluent.
The appropriate volume of the infusion bag is calculated as follows:

[Required dose (mg)/final concentration (mg/mL)] – Volume of the concentrate (mL)

The concentrate can be diluted with either 9 mg/mL (0.9%) sodium chloride solution for injection or 50 mg/mL (5%) dextrose solution.

Administration

After the reconstituted concentrate is further diluted, the diluted solution may show fine white-to-translucent particulates of isavuconazole that do not sediment (but will be removed by in-line filtration). The diluted solution should be mixed gently, or the bag should be rolled to minimise the formation of particulates. Unnecessary vibration or vigorous shaking of the solution should be avoided. The solution for infusion must be administered via an infusion set with an in-line filter (pore size 0.2 µm to 1.2 µm) made of polyether sulfone (PES). Infusion pumps can be used and must be placed before the infusion set. Regardless of the infusion solution container size used, the entire volume of the container should be administered to ensure the complete dose is administered.

Isavuconazole should not be infused into the same line or cannula concomitantly with other intravenous products.

Chemical and physical in-use stability after reconstitution and dilution has been demonstrated for 24 hours at 2 °C to 8 °C, or 6 hours at room temperature.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C, unless reconstitution and dilution has taken place in controlled and validated aseptic conditions.

If possible, the intravenous administration of isavuconazole should be completed within 6 hours after reconstitution and dilution at room temperature. If this is not possible, the infusion solution should be immediately refrigerated after dilution, and infusion should be completed within 24 hours.

An existing intravenous line should be flushed with sodium chloride 9 mg/mL (0.9%) solution for injection or 50 mg/mL (5%) dextrose solution.

This medicinal product is for single use only. Discard partially-used vials.